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## Summary of Safety and Effectiveness

This summary of safety and effectiveness was originally prepared by Technical Chemicals and Products Inc. for inclusion in its One Step™ Pregnancy hCG strip. This represents an expansion of the intended use to include both serum and plasma as well as urine. For any questions contact Dr. Cleve W. Laird, Exec. V.P., Technical Chemicals and Products Inc. at 954-971-7595. The Predicate device is One Step™ Pregnancy hCG strip a class II device cleared under 510K # 934830.

The Technical Chemicals and Products Inc. ("TCPI") One Step™ Pregnancy hCG strip assay is a qualitative, sandwich dye conjugate immunoassay for the determination of Human Chorionic Gonadotropin in urine or serum. The method employs a unique combination of monoclonal and polyclonal antibodies to selectively identify hCG in test samples with a high degree of sensitivity using a unique patented membrane technology. In less than 5 minutes, elevated levels of hCG as low as 25 mIU/ml can be detected. If the test is to be used on serum the sample must be diluted according to the directions for the One Step™ Pregnancy hCG serum diluent (cat XXXXX).

As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band when hCG concentration is greater than 25 mIU/ml. In the absence of hCG, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive reaction zone and negative zone. Unbound conjugate binds to the reagents in the negative control zone, producing a pink-rose (magenta) color band, demonstrating that the reagents and device are functioning correctly.

The TCPI One Step™ Pregnancy hCG strip hCG test has been extensively tested against substances known to interfere with pregnancy testing with no apparent interferences. The specificity of the reaction has been tested against other hormones with no cross reactivity noted. The sensitivity of the product is routinely tested and found to be 25 mIU/ml [See Stability testing]. When tested blind in 150 documented (Pregnant/not pregnant) patient samples the test correctly identified all 150 samples (90 pregnant and 60 not pregnant). There were no false negatives or positives. TCPI has produced and distributed in excess of 19,604,093 strips World wide for the past four (4) years with very few complaints. All of the complaints have been related to shipping problems between the foreign distributor and the retail outlets or not following the directions for use.

In a series of clinical trials the combination of the diluent reagent and One Step™ Pregnancy hCG Strip were compared to reference methods and samples (urine and serum/plasma) In all 385 patient comparisons the results of the diluent reagent plus the One Step™ Pregnancy hCG strip agreed with the reference methods employed in the studies. Based upon the results of the clinical testing the accuracy, sensitivity, and specificity all equal 100%.